To the Epilepsy Foundation,

The Epilepsy Foundation of America's mission statement claims a mandate to "prevent, control and cure epilepsy through services, education, advocacy and research." I am hopeful that you can be of assistance in helping me to further this goal.

I believe that there is an effective treatment option for epilepsy with negligible risk that is currently being overlooked, and you have an opportunity to help open the door for millions of epilepsy patients. I am writing to you seeking your help in asking the American Academy or Neurology (AAN) and the American Epilepsy Society (AES) for the key.

Background

EEG-based Operant Conditioning (also known as neurofeedback[1]) is a neuromodulation technique that, under clinical guidance, allows patients to train their own brains toward greater stability. By virtue of our intrinsic brain plasticity, the brain can actually learn to alter its own operating characteristics. The result can be greater tolerance for the side effects of anti-epileptic drugs (AEDs); it can be a higher quality of life; and it can even mean a reduction or elimination of seizures that have not responded to medication.

Neurofeedback has been under development since the 1960s with animal research. The first evidence for efficacy against chemically induced seizures was found with cats and with monkeys. There have been many studies done over the years with varying degrees of scientific rigor.[2, 3, 4, 5]

In a review of the state of the field in 2000, M. Barry Sterman surveyed 20 group studies covering 25 years, and determined that 82% of subjects improved by at least 30% in seizure incidence; the average improvement was >50%; and five percent became seizure-free for at least a year post-training, despite reductions or even complete elimination of AEDs.[5] Some 13 of these studies included competent controls and A-B-A designs. Since then, there have been improvements to the training protocols (such as QEEG-guided neurofeedback) yielding even better results (~95% of refractory epilepsy patients achieving 100% seizure control for an average of 7 years).[6, 7]

Adverse reactions to neurofeedback training are overall rare, and when they occur they are relatively transient or readily dealt with by competent practitioners.[8, 9] There are no health risks associated with clinical neurofeedback.

The Quest for the Threshold

I asked Dr. Steven Schachter, current President of the AES, what it would take to accept neurofeedback as a mainstream treatment option during an internet radio talk show recently.[10] He identified several key points that any treatment should meet in order to be considered a valid option:

- Potential benefits identified
- Potential risks identified
- Results can generally be believed (effects likely to be a result of the treatment)
- Ability to individualize the application (ie. Tie the treatment to a specific diagnosis)

Dr. Schachter also stated, (paraphrasing) "if a form of treatment has been thoroughly studied and the associated risks seem to be minor or non-existant, then the benefit that would need to come from that is not necessarily as definitive as you would expect if you were recommending a treatment that has significant risks." [10]

It is my contention that neurofeedback meets Dr. Schachter's criteria at least as well as another treatment option that is currently touted as a viable treatment option for refractory epilepsy.

Comparison of Neurofeedback and Vagus Nerve Stimulator Research

Cyberonics' Vagus Nerve Stimulator (VNS) underwent five clinical trials before being approved by the FDA as a treatment option for epilepsy. According to *Neurology* [11] :

> "Inclusion and exclusion criteria for the five acute-phase studies varied, but all the studies included patients who desired an alternative treatment for their seizures and patients who had persistent seizures despite appropriate medical management. The baseline frequency of seizures varied among the studies. Partial seizures were required in E01/2, E03, and E05 studies. Generalized seizures were allowed in E04 (n = 25). …"

Further digging into the details shows that patients in the studies altered medication regimens during the course of the trials as well.

The research supporting the VNS is not much different from the research supporting neurofeedback. They both exhibit common traits:

- there are no narrowly-defined inclusion criteria except for "patients who desired an alternative treatment for their seizures and patients who had persistent seizures despite appropriate medical management"
- varying baseline incidence of seizures
- some studies did not include suitable controls

It's been established that there are no health risks for neurofeedback[8, 9]. The benefits of neurofeedback appear to be more effective than the VNS for the same loosely defined (refractory epilepsy) patient population. [2,3,4,5,6,7,11]

Neurofeedback produces measurable changes in the way the brain functions. This can be seen with QEEG mapping and other diagnostic tools. The changes in brain function are correlated with improvements in seizure control. In contrast, the VNS was FDA approved and is accepted even though no one knows how or why it works.[12,13]

Is this rational?

The VNS has been recommended to patients with refractory/intractable tonic clonic (generalized) seizures. There is no basis for this in the published studies unless a patient population of 25 people (from the E04 study) is considered sufficient. If that is the case, why is the same consideration not extended to a therapy option that appears to be more effective and with non-existent, or certainly lower health risks?

The FDA said it expedited its review/approval of the VNS "because of its potential importance for reducing seizures in people who lack effective, alternative treatment"[14]. Why does not the AAN and AES give the same consideration to neurofeedback? Why is there not an ethical obligation to try a non-invasive therapy before an invasive treatment is considered?

The Bottom Line

I am reaching out to you to ask the AAN and AES to define clear threshold criteria for accepting neurofeedback as a mainstream treatment option for epilepsy. I would be very happy to spearhead the effort to organize a research program aimed at meeting any AAN/AES threshold requirements that might be established. I am in contact with some neurologists here in the USA who are using neurofeedback successfully and who would be happy to participate in such research. I am also in contact with epilepsy research foundations who are intrigued by the project and are willing to consider funding the effort pending a good design.

Why am I asking for help from the EFA in this matter? Institutional support would be much more able to mobilize critical opinion within the medical community than my own individual effort. I have also contacted the AAN directly, and I am still awaiting their response.[15] I hope that in view of your close relationship with the AAN/AES, you might be able to elicit a thoughtful response from the medical community.

Neurofeedback is not a patentable drug nor an implantable medical device. No one "owns" it. There is no singular commercial interest pushing for it like there are for new drugs and medical implant devices. If the epilepsy community doesn't push for action, it will remain overlooked. I would appreciate any assistance the EFA could lend in seeking a resolution on this issue for the benefit of all epilepsy patients.

Cordially,
Bernard Ertl
www.coping-with-epilepsy.com

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